

Message Text

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PAGE 01 STATE 073490
ORIGIN HEW-06

INFO OCT-01 ARA-10 EUR-12 EA-09 ISO-00 OES-06 EB-08
COME-00 STR-04 /056 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/PHS/OASH/OIH: RFISCHER
EA/EX:EECHAMPAGNE(INFO)
EUR/EX:JLTULL(INFO)
ARA/EX:RSGERSHENSON(INFO)
-----030756Z 042836 /10

P R 022151Z APR 77
FM SECSTATE WASHDC
TO AMEMBASSY CANBERRA PRIORITY
AMEMBASSY VIENNA PRIORITY
AMCONSUL RIO DE JANEIRO PRIORITY
AMEMBASSY TOKYO PRIORITY
AMEMBASSY THE HAGUE PRIORITY
AMEMBASSY MADRID PRIORITY
AMEMBASSY LONDON PRIORITY
INFO AMEMBASSY BRASILIA

UNCLAS STATE 073490

E.O. 11652: N/A

TAGS: SP,UK,OGEN, ETRD, EIND, TBIO, AS, AU, BR, JA, NL

SUBJECT: FDA ADVISORY - INCORRECT PROGRAM CARD FOR
DIAGNOSTIC MEDICAL DEVICE (RECALL T-078/079-7)

1. FDA ADVISES OF THE FOLLOWING RECALL:

PRODUCT INVOLVED: SGOT AND SGPT "SPIN CHEM" MAGNETIC PROGRAM CARDS (PRODUCT NUMBERS 85207 AND 85208). THESE MAGNETIC PROGRAM CARDS PERMIT THE USE OF SMITH KLINE INSTRUMENTS, INC. SGOT (SERUM GLUTAMIC OXALOACETIC TRANSAMINASE) AND SGPT (SERUM GLUTAMIC PYRUVIC TRANSAMINASE) "SPIN CHEM" IN-VITRO DIAGNOSTIC REAGENTS IN THE GILFORD SYSTEM 3500 FOR THE DETERMINATION OF TRANSAMINASE LEVELS IN HUMAN SPECIMENS.

UNCLASSIFIED

PAGE 02 STATE 073490

MENTS, INC. SGOT (SERUM GLUTAMIC OXALOACETIC TRANSAMINASE) AND SGPT (SERUM GLUTAMIC PYRUVIC TRANSAMINASE) "SPIN CHEM" IN-VITRO DIAGNOSTIC REAGENTS IN THE GILFORD SYSTEM 3500 FOR THE DETERMINATION OF TRANSAMINASE LEVELS IN HUMAN SPECIMENS.

MANUFACTURER: GILFORD INSTRUMENT LABORATORIES, INC.
- 132 ARTINO STREET

- OBERLIN, OHIO 44074
- SMITH KLINE INSTRUMENTS, INC.
- 880 WEST MAUDE AVENUE
- SUNNYVALE, CALIFORNIA 94086

RECALLING FIRM: SMITH KLINE INSTRUMENTS, INC.

- 880 WEST MAUDE AVENUE
- SUNNYVALE, CALIFORNIA 94086

2. REASON FOR RECALL:

ON 12/23/76 A CUSTOMER REPORTED THEY WERE NOT GETTING THE IA (INITIAL ABSORBANCE) FLAG WITH PATIENT SAMPLES WHICH SEEMED TO BE EXHAUSTING THE SUBSTRATE OF THE REAGENT. A SECOND COMPLAINT OF A SIMILAR NATURE WAS RECEIVED ON 1/4/77, INVESTIGATION BY THE FIRM DETERMINED THAT THERE WAS AN OMISSION OF THE IA FLAG IN THE PROGRAM CARD WHICH TELLS THE USER THAT THE SUBSTRATE OF THE REAGENT IS EXHAUSTED RESULTING IN POSSIBLE INVALID TEST RESULTS (IT MAY CAUSE A HIGHLY ABNORMAL SAMPLE TO PRINT OUT AS A LOW NORMAL OR SUBNORMAL VALUE.)

THE SGOT AND SGPT REACTIONS RESULT IN DECREASING ABSORBANCE. A HIGH SAMPLE REACTING QUICKLY WILL DECREASE THE ABSORBANCE OF THE REACTION MIXTURE RAPIDLY AND EXHAUST THE SUBSTRATE. THE IA FLAG, WHEN OPERATIVE, TELLS THE OPERATOR THAT THE ABSORBANCE HAS PASSED BELOW 0.8A INDICATING THAT THE SAMPLE ACTIVITY IS TOO HIGH TO BE DETERMINED

UNCLASSIFIED

PAGE 03 STATE 073490

WITH SUBSTRATE PRESENT AND THAT SUBSTRATE EXHAUSTION HAS OCCURRED. SUBSTRATE EXHAUSTION ALSO MANIFESTS ITSELF AS AN EXTREMELY LOW RATE--AS A SUBNORMAL SAMPLE. THUS, SAMPLES WHICH MAY ACTUALLY HAVE EXTREMELY HIGH CONCENTRATION OF OT/PT GAVE A NORMAL OR SUBNORMAL ANSWER ON THE PRINT OUT.

3. POSTS ARE REQUESTED TO CONTACT CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED RECALL TELEX OF JANUARY 31, 1977 INSTRUCTING THEM TO IMMEDIATELY STOP USING DEFECTIVE CARDS AND TO RETURN THEM TO SMITH KLINE INSTRUMENTS, INC. FIRM ALSO SENT FOLLOW-UP LETTER TO TELEX OF JANUARY 31, 1977. ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING RECALL SHOULD BE DIRECTED TO RECALLING FIRM.

4. CONSIGNEES AS FOLLOWS:

SMITH KLINE AND FRENCH, LTD
FRENCH S. FOREST N.S.W., AUSTRALIA

SMITH KLINE INSTRUMENTS, GMBH
AUSTRIA

FORMED
RIO DE JANEIRO, BRAZIL

EIKEN CHEMICAL COMPANY, LTD
TOKYO, JAPAN

GIST-BROCADES
DELFT, THE NETHERLANDS

IZASA, S.L.
BARCELONA, SPAIN
(DEALER: SPAIN)

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PAGE 04 STATE 073490

SMITH KLINE INSTRUMENTS, INC
HERTFORDSHIRE, ENGLAND
VANCE

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Sent Date: 02-Apr-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE073490
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770115-1167
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t19770494/aaaadebr.tel
Line Count: 142
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 1e5501ab-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 3
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 05-Jan-2005 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 2916377
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - INCORRECT PROGRAM CARD FOR DIAGNOSTIC MEDICAL DEVICE (RECALL T-078/079-7)
TAGS: OGEN, ETRD, EIND, TBIO, SP, UK, AS, AU, BR, JA, NL
To: CANBERRA VIENNA MULTIPLE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/1e5501ab-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
22 May 2009
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009